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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/943,115 | 08/30/2001 | Carl Risinger | 524592002100 | 9958 |

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BIOTECHNOLOGY LAW GROUP
c/o PORTFOLIO IP
P.O. BOX 52050
MINNEAPOLIS, MN 55402

| EXAMINER | |
|---|---|
| O'FARRELL, THOMAS JOHN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/943,115 | RISINGER ET AL. | |
| | Examiner | Art Unit | |
| | Thomas J. O'Farrell | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/30/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *sequence search results*.

## DETAILED ACTION

1. Please note that the examiner of record has changed regarding this application. Please address all further correspondences to Thomas O'Farrell whose contact information is noted as the end of this office action.

### *Election/Restrictions*

2. Claims 9-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election of group I, claims 1-8, was made **without** traverse in the reply filed on 7/16/2003. Additional species elections of SEQ ID NO:s 7 and 8 were made regarding instant claims 2 and 6 and SEQ ID NO:s 15 and 16 regarding instant claims 4 and 8. SEQ ID NO:s 7 and 8 were found to be free of prior art with regard to the limitations of instant claims 2 and 6 and therefore SEQ ID NO:s 9 and 10 were searched with regard to the limitations these claims as well. Prior art relating to SEQ ID NO:s 15 and 16 with regard to the limitations of instant claims 4 and 8 was found and therefore there was no further search of other species within this group. Claims 1-8 are currently under consideration. An action on the merits follows.

***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 8/30/2000. It is noted, however, that applicant has not filed a certified copy of the 0021286.0 application as required by 35 U.S.C. 119(b). Therefore, priority to the 0021286.0 application has not been granted for the instantly pending claims.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claims 1 and 5 are drawn to oligonucleotide primers suitable to amplify the polymorphic region corresponding to position 461 of SEQ ID NO:1. The examiner interprets "a polymorphic region of a 5' flanking region of a CYP3A4 gene, wherein the polymorphic region corresponds to position 461 of SEQ ID NO:1" (instant claim 1) or

"the region corresponding to position 461 of SEQ ID NO:1" (instant claim 5) as any sequence of DNA encompassing position 461 of SEQ ID NO:1 or is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. In addition, it is unclear what DNA sequences define the "5' flanking region of a CYP3A4 gene". Therefore, although the specification teaches oligonucleotide primers SEQ ID NO's:7-10, instant claims 1 and 5 encompass a large genus of oligonucleotide primer pairs that hybridize to any region of the same continuous piece of DNA, human chromosome 7 for example (see Sata, et al., (2000), *Clin. Pharmacol. Ther.*, vol 67, page 49, paragraph 1, line 21), containing position 461 of SEQ ID NO:1 which have not been taught or described in the specification. This large genus further encompasses variant primers that may hybridize to complementary DNA sequences under various stringency conditions, which have not been taught or described in the specification. In addition, at the time of filing of the invention, human chromosome 7, which encompasses position 461 of SEQ ID NO:1, was not fully sequenced and assembled (see Scherer, et al., (2003), *Science*, vol. 300, page 767, paragraph 2, lines 1-3) and therefore one of skill in the art would not have had adequate guidance for designing many of the oligonucleotide primers encompassed by this genus. The disclosure of the oligonucleotide primers SEQ ID NO's:7-10 is not representative of the broad variable genus of nucleic acids encompassed by the claims as now pending.

Instant claims 3, 4, 7 and 8 are drawn to oligonucleotides complementary to the polymorphic region corresponding to position 461 of SEQ ID NO:1. The examiner interprets the "oligonucleotide (being) complementary to the polymorphic region

corresponding to position 461 of SEQ ID NO:1" as an oligonucleotide complementary to any sequence of DNA encompassing position 461 of SEQ ID NO:1 or is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. Therefore, although the specification teaches oligonucleotides consisting of SEQ ID NO's:15 and 16, instant claims 3, 4, 7 and 8 encompass a large genus of oligonucleotide primer pairs that hybridize to any region of the same continuous piece of DNA, human chromosome 7 for example, containing position 461 of SEQ ID NO:1 which have not been taught or described in the specification. Also, this large genus further encompasses many mutant and variant oligonucleotides that may hybridize to complementary DNA sequences under various stringency conditions, which have not been taught or described in the specification. Additionally, instant claims 4 and 8 recite sequences *comprising* SEQ ID NO's:15 and 16. However, SEQ ID NO's: 15 and 16 each consist of only 11 nucleic acids, which would be expected to occur a large number of times in any genome. The claims therefore actually encompass sequences from any chromosome from any genome of any species, including variants and homologs, that have not been taught or described in the specification. For example, DNA encoding fish neuropeptides are encompassed by the instantly pending claims, which are not taught or described in the specification (sequence 33 of US Patent 5,695,954 also contains the polynucleotide sequences of SEQ ID NO:15; see result 4 from SEQ ID NO:15 search results from Issued Patent database, alignment with sequence from US Patent 5,695,954). The disclosure of the oligonucleotide primers consisting of SEQ ID NO's:15

and 16 is not representative of the broad variable genus encompassed by the claims as written.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO's:7-10 and 15 and 16, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the

written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what DNA sequences define the "5' flanking region of a CYP3A4 gene" (instant claims 1-4). In addition, the instant claims recite a "polymorphic region" that "corresponds" (instant claims 1 and 2) or is "corresponding to" (instant claims 3, 4, 7, and 8) position 461 of SEQ ID NO:1 and a "region corresponding to position 461 of SEQ ID NO:1" (instant claims 5 and 6). In lines 1 and 2 of paragraph 2 on page 8 of the specification, a polymorphic region is defined as a portion of a genetic locus that is *characterized* by at least one polymorphic site. However, lines 5-8 of the specification state that a "polymorphic region as defined herein is said to "correspond to" a polymorphic site, that is, the region may be adjacent to the polymorphic site on the 5' side of the site or on the 3' side of the site, or alternatively may *contain* the polymorphic site". These two recitations of the specification appear to contradict one another. The definition of a polymorphic region and its relationship to a polymorphic site is unclear. It is unclear whether the

polymorphic region contains the polymorphic site or can be a region *anywhere* on the same continuous piece of DNA containing the polymorphic site that does not actually encompass the polymorphic site. As such, it cannot be determined if additional sequences from SEQ ID NO:1 (other than position 461) are encompassed by the claim, and if so, how much of SEQ ID NO:1 is encompassed by the claimed sequences. Clarification is required.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

With regard to the following rejections under 35 U.S.C. 102, the examiner's interpretation of the relevant claims is as follows. Regarding instant claim 1, the examiner interprets "a polymorphic region of a 5' flanking region of a CYP3A4 gene, wherein the polymorphic region corresponds to position 461 of SEQ ID NO:1" as any sequence of DNA encompassing position 461 of SEQ ID NO:1 *or* is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. Regarding instant claim 3, the "oligonucleotide being complementary to the polymorphic region corresponding to position 461 of SEQ ID NO:1" is interpreted as an

oligonucleotide that is complementary to any sequence of DNA encompassing position 461 of SEQ ID NO:1 or is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. Regarding instant claim 5, the "region corresponding to position 461 of SEQ ID NO:1" is interpreted as any sequence of DNA encompassing position 461 of SEQ ID NO:1 or is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. Regarding instant claim 7, the "oligonucleotide complementary to the polymorphic region corresponding to position 461 of SEQ ID NO:1" is interpreted as an oligonucleotide that is complementary to any sequence of DNA encompassing position 461 of SEQ ID NO:1 or is adjacent to, without any regard to distance from position 461 of SEQ ID NO:1, position 461 of SEQ ID NO:1. Also, a "sequence determination oligonucleotide" as recited in instant claims 3 and 7 is interpreted as any oligonucleotide that can be used in any process of determining a sequence such as a PCR primer, a primer used for direct sequencing, or an allele specific probe.

7. Claims 1, 3-5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodwin et al. (herein referred to as Goodwin, *Molecular Pharmacology*, vol. 56, pages 1329-1339, 12/1999).

It is noted that the polymorphism at position 461 of SEQ ID NO:1 recited in instant claims 1, 3, 5, and 7 corresponds to position –644 from the transcription start site of the CYP3A4 gene as taught on page 5, paragraph 2, lines 2-5 of the specification. However, position 461 of SEQ ID NO:1 corresponds to position –656 in

the numbering system used by Goodwin to denote positions of nucleotides from the transcription start site of the CYP3A4 gene (see Gen Bank/EMBL/DDBJ accession number AF185589, bases –10468 to +906 of the CYP3A4 gene). Goodwin teaches an oligonucleotide primer pair used to amplify region +53 to –1084 of the CYP3A4 gene (instant claims 1 and 5; see page 1330, paragraph 7, lines 2-8 of Goodwin). It is noted that the polymorphism at position 461 of SEQ ID NO:1 is encompassed by this region and that these primers could be used to detect this polymorphism by direct sequencing (instant claims 1, 3, 5 and 7). Goodwin also teaches the production of the following DNA fragments containing sequences of the CYP3A4 gene that would hybridize to DNA sequences encompassing or adjacent to position 461 of SEQ ID NO:1: -1084 to +53, -362 to +53, -3195 to –1310, and -1310 to -362 (instant claims 3 and 7; see page 1330, paragraph 7, lines 2-18 of Goodwin). These sequences were generated from bases –10468 to +906 of CYP3A4 (Gen Bank/EMBL/DDBJ accession number AF 185589, see page 1330, paragraph 6, lines 11-14 of Goodwin). It is noted that the above listed fragments -1084 to +53 and -1310 to –362 contain the nucleic acid sequences of SEQ ID NO:s 15 and 16 (instant claims 4 and 8). Positions –669 to –659 of Gen Bank/EMBL/DDBJ accession number AF 185589 are identical to SEQ ID NO:s 15 and 16 (SEQ ID NO:15 being the compliment of SEQ ID NO:16) (see Gen Bank/EMBL/DDBJ accession number AF 185589). With regard to the recitation of "kit" in instant claims 5, 7, and 8, as the claims do not recite any additional structural limitations that would distinguish the "kit" from a composition comprising a primer pair or

a probe, the compositions containing the primer pair or probes taught by Goodwin anticipate the claimed "kits".

8. Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Lichter (herein referred to as Lichter, WO 99/13106, 03/1999).

Lichter teaches a polymorphism at position –392 of the CYP3A4 gene (see page 15, paragraph 4, lines 3 and 4 of Lichter). Lichter teaches that the numbering system for such position is with reference to the start codon. This polymorphism is denoted "r" at position 816 of SEQ ID NO:3 taught by Lichter (It is noted that position 461 of SEQ ID NO:1 of the instant claims is the same as position 461 of SEQ ID NO:3 as taught by Lichter). Therefore, position 461 in the claims of the instant application would be numbered as position –747, using the numbering system of Lichter.

Lichter teaches oligonucleotide primer pairs to amplify regions –331 to –442 and –483 to +210 which contain the polymorphism taught by Lichter, and are adjacent to position 461 (-747 if using Lichter's numbering system) of SEQ ID NO:1 of the instantly pending claims (instant claims 1 and 5; see page 15, paragraph 3, lines 3-7 and Table 1 of Lichter). The primer pairs and amplified sequences of Lichter therefore read on regions "corresponding" to position 461 of SEQ ID NO:1 as broadly encompassed by the instantly pending claims. These primers could be used to detect the polymorphism at position –392 by direct sequencing (instant claims 3 and 7). Lichter also teaches oligonucleotides that hybridize to sequences encompassing position –392 of the CYP3A4 gene, which are adjacent to position 461 of SEQ ID NO:1 (instant claims 3 and

7; see page 15, paragraph 3, lines 7-10 of Lichter). Lichter teaches that these oligonucleotides can be used to detect the polymorphism at position –392 of the CYP3A4 gene using TaqMan technology (instant claims 3 and 7; see page 15, all of paragraph 3 of Lichter). Lichter also teaches oligonucleotide primer pairs used to amplify various other regions of the CYP3A4 gene, which are adjacent to position 461 of SEQ ID NO:1, containing polymorphisms and sequencing primers used to identify the polymorphisms within these regions (instant claims 1, 3, 5, and 7; see Tables 1-3 of Lichter). With regard to the recitation of "kit" in instant claims 5 and 7, as the claims do not recite any additional structural limitations that would distinguish the "kit" from a composition comprising a primer pair or a probe, the compositions containing the primer pair or probes taught by Lichter anticipate the claimed "kits".

9. Claims 1, 3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Paulussen et al. (herein referred to as Paulussen, *Pharmacogenetics*, vol. 10, pages 415-424, 07/2000), as defined by Jounaidi et al. (herein referred to as Jounaidi, *Biochem. Biophys. Res. Commun.*, vol. 205, pages 1741-1747, 12/1994).

Jounaidi teaches that CYP3A5 and CYP3A4 are located on chromosome 7 (see page 1741, paragraph 1, lines 1-3 of Jounaidi) (see page 136, paragraph 1, lines 9 and 10 of Inoue) and therefore regions of the CYP3A5 gene, including the promoter region, are adjacent to position 461 of SEQ ID NO:1 and read on regions "corresponding" to position 461 as broadly encompassed by the instant claims. Paulussen teaches oligonucleotide primers, 3A51 and 3A52, used to amplify a part of the 5' prime flanking

region of the CYP3A5 gene (instant claims 1 and 5; see page 417, paragraph 4, lines 1-6 of Paulussen). It is noted that this region contains several polymorphisms and that primer 3A51 can be used to detect some of these polymorphisms by direct sequencing (instant claims 3 and 7; see Tables 1 and 2 of Paulussen). Paulussen also teaches several oligonucleotide primers that can be used to detect polymorphisms in the CYP3A5 gene (instant claims 3 and 7; see Table 1, page 417, all of paragraph 5 and page 418, all of paragraphs 1-3 of Paulussen). With regard to the recitation of "kit" in instant claims 5 and 7, as the claims do not recite any additional structural limitations that would distinguish the "kit" from a composition comprising a primer pair or a probe, the compositions containing the primer pair or probes taught by Paulussen anticipate the claimed "kits".

10. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al. (herein referred to as Bauer, EP Publication 0269127-A, 01/1988). See attached result #3 of oligonucleotide search of SEQ ID NOs:15 and 16 in the GenEmbl database.

Bauer teaches oligonucleotides that comprise the sequences of SEQ ID NO:15 and 16 (claims 3 and 4; see attached result #3 of oligonucleotide search of SEQ ID NO:15 and 16 in GenEmbl database showing alignment).

***Conclusion***

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas O'Farrell whose telephone number is (571) 272-8782. The examiner can normally be reached Monday-Friday from 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Thomas O'Farrell
Examiner
Art Unit 1634
8/5/2005

JEHANNE SITTON
PRIMARY EXAMINER
8/5/05